UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

CAROL LEWIS
25 Old Harbor Rd.
Chatham, MA 02633

Plaintiff,

v.

Civil Action No. 15-13530-NMG

SYLVIA BURWELL in her official capacity
as Secretary, United States Department
of Health and Human Services,
615-F Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201,

Defendant.

RESPONSE TO DEFENDANT'S MOTION TO DISMISS

I. INTRODUCTION

By this action, Plaintiff, Carol Lewis, a Medicare beneficiary, challenges a decision ("the Decision") issued by Defendant, the Secretary of Health and Human Services ("HHS"), denying Medicare coverage under 42 U.S.C. §1395y(a), for claims relating to a continuous glucose monitor, an item of durable medical equipment ("DME"). This Court must decide whether the Decision is arbitrary and capricious, not based on substantial evidence, or otherwise unlawful under the Administrative Procedure Act ("APA"), 5 U.S.C. §551 *et seq*, and, therefore, must be set aside. Further, this Court must decide whether mandamus is appropriate given the Secretary's failure to adhere to statutory timelines.

Rather than filing and certifying the administrative record to allow both parties to file their motions for summary judgement, and despite requesting an extension to enable her to produce the administrative record and file a complete answer (Dkt. 10), the Secretary filed a Motion to Dismiss ("Def. Motion") Dkt. 12, and Memorandum of Law in Support thereof ("Def. Mem."). Dkt. 13.

II. ARGUMENT

The gravamen of the Secretary's Motion to Dismiss is (1) Ms. Lewis has not exhausted her administrative remedies through the local coverage determination ("LCD") challenge process; (2) no judicial review of individual claims is available; and (3) mandamus is an extraordinary remedy not available to Ms. Lewis. Each contention is contrary to the relevant statutes and regulations and the Secretary's public assertions and interpretations thereof.

A. Federal Jurisdiction Derived from the Claims Appeal Process is Distinct from the LCD Challenge Process

The Secretary badly misstates the law when she asserts that this court does not have jurisdiction because a separate action, Ms. Lewis' challenge to the relevant LCD, has not yet resulted in a final agency determination. The Secretary has long recognized the distinction between a claim appeal (which does *not* challenge the validity of an LCD) and the LCD challenge and reconsideration processes. *See* 67 Fed. Reg. 54536-37 (Aug. 22, 2002); 68 Fed. Reg. 63393-94 (Nov. 7, 2003) ("Section 522 of the BIPA [the Benefits Improvement and Protection Act] created a [LCD] review process that is separate and independent from the claims appeal process. This process will be different, because the nature of the challenge and relevant evidence is different. The procedures used from this process will be distinct from the claims appeal process. . . In no way does filing a 522 [LCD] challenge, or a decision in a 522 challenge,

affect beneficiary appeal rights or other issues that may arise in the claims appeal process."); *see also,* 68 Fed. Reg. 63707 (Nov. 7, 2003) ("LCD and NCD reviews are largely independent of the claims appeal processes."). Contrary to the Secretary's assertions, a Medicare beneficiary can appeal a denied claim to a district court independent of and regardless of the status of an LCD challenge.

In fact, a cursory review of District Court actions reveals that most beneficiaries do not file an LCD challenge when seeking Medicare coverage of services. This is because an LCD is not binding on Medicare's Administrative Law Judges ("ALJs") or the Medicare Appeals Council ("AC"), and Medicare coverage can be found for individual claims, regardless of language in an LCD, if a device is reasonable and medically necessary based on a Medicare beneficiary's condition. 42 C.F.R. §§ 405.1062. With respect to CGM, numerous ALJs have found CGM to be reasonable and medically necessary for Medicare beneficiaries notwithstanding a Medicare contractor's unsupported statement that CGM is "precautionary." See, e.g. Attached representative ALJ decisions finding coverage of CGM, appended hereto for convenience. Each of those decisions constitutes the Secretary's final determination with respect to those CGM claims.

B. Judicial Review is Available Under the Administrative Procedures Act

The Secretary's assertion that judicial review of an individual claim is not available is contradicted by her own filing. The Secretary concedes the judicial review is available for individual claims under 42 C.F.R. §§405.1130, 405.1136. See Def. Mem. at 5. Nonetheless, the Secretary perversely argues that judicial review is not available. Def. Mem. at 11 – 12. The statutory and regulatory construct specifically provide for judicial review of individual claim decisions, i.e., the Medicare Act specifically grants judicial review of individual claim

determinations. Here again, the Secretary conflates LCD challenge and review with individual claim review and fails to appreciate that Ms. Lewis has channeled her claim through agency review and has exhausted it – she has received a final determination from the AC. Contrary to the Secretary's assertions, Ms. Lewis has asserted that the denial is not supported by substantial evidence and is arbitrary and capricious. Complaint at ¶¶14, 106, 107, 109, 114, 116, 119, 122, 126.

The Secretary also asserts, contrary to law, that "claims arising under the Medicare Act are not reviewable under the APA because other statutory review is provided under the Medicare Act." Def. Mem. at 11. Again, the Secretary ignores her own regulations which explicitly provide for judicial review, a long line of cases finding such review is available under the APA, 5 U.S.C. §706 for individual Medicare claims, and her numerous public pronouncements and program instructions indicating district court review is available for individual claims.[1] Thus, the Secretary's assertions are contrary to black letter law, numerous cases that have found judicial review is available under the APA for individual claims, and numerous public comments advising Medicare beneficiaries of the same.

It appears the Secretary misapprehends the review available under 5 U.S.C. §706. Not only does it accord review as to whether the Secretary's final decisions are arbitrary and capricious, it supports review as to whether the Secretary's decision is supported by substantial evidence. See 5. U.S.C. §706(2)(E) (providing a court shall set aside agency action not supported by substantial evidence).

If the Secretary had filed the administrative record, as is required under the APA, she would have appreciated that no evidence, let alone substantial evidence, supports the denial of

[1] See, e.g., https://www.medicare.gov/claims-and-appeals/file-an-appeal/appeals-level-5.html clearly stating judicial review is available for individual claims; dicare/appeals-and-grievances/orgmedffsappeals/review-federal-district-court.html; Medicare Claims Processing Manual, Ch. 29, §345.

Ms. Lewis' claim.[2] The Medicare Appeals Council ("AC") simply relied on the LCD/LCA when denying the claim although the Medicare Civil Remedies Division has found that substantial evidence does not support the relevant Medicare contractor's contention that CGM is "precautionary" for individuals such as Ms. Lewis.[3] Thus, because the AC premised the denial of Ms. Lewis' claim for CGM based solely on the Medicare contractor's statement that CGM is "precautionary," and that statement has been determined not to be supported, the LCD/LCA is entitled to no deference and the MAC's rationale, premised solely on the LCD/LCA is flawed.[4] In the absence of an LCD, coverage is determined based on the literature, medical opinion and the reasonableness of the device. Ms. Lewis has submitted overwhelming evidence (including literature, expert opinion, acceptance by the relevant medical community) in support of coverage generally and her particular need for CGM. Her clinician, an expert in diabetes care and management, testified in support of CGM coverage generally and specifically in support of Ms. Lewis' need for CGM. No contrary medical opinion was offered. In contrast nothing in the administrative record supports the MAC's denial which reflects circular logic – because NHIC states (albeit without support) that CGM is precautionary, it is not durable medical equipment ("DME") and thus not covered under Medicare's DME benefit. The MAC affirmed finding that based on CGM's precautionary status, it is not medical equipment and not DME and thus

[2] The Secretary requested a 45 day extension to enable production of the administrative record, but did not produce the administrative record as required, and, having been granted an extension, has a motion asserting that production of the administrative record was not necessary for her filing.

[3] In fact, based on the reasonableness analysis, the ALJ awarded discovery and ordered the parties to submit all documents and witnesses that they wished to have considered during the final reasonableness review. NHIC's documents, witnesses and a brief on all the legal and factual issues were due on January 15, 2016 - NHIC proposed not a single document or witness in support of the LCD/LCA and did not submit a brief in defense of the LCD/LCA. In response to an interrogatory, NHIC conceded that it relied on no medical opinion when it asserted CGM is precautionary.

[4] Because the LCD/LCA has been determined not to be supported by substantial evidence, Ms. Lewis is entitled to adjudication of her claim without reference to the LCD/LCA. The Secretary notes that Ms. Lewis' pre-hearing submission in the LCD challenge process was due by February 16, 2016. However, Ms. Lewis already submitted voluminous documents and witnesses and a brief in support of her challenge. Because NHIC submitted no evidence, and Ms. Lewis submitted overwhelming evidence in support of her challenge, the ALJ should allow Ms. Lewis' motion for summary judgement.

statutorily excluded. However, the statement that CGM is precautionary and not medical equipment and thus not DME is belied by the administrative record. All of the evidence is to the contrary.

C. Mandamus is Appropriate

1. The Administrative Remedy of Escalation is No Remedy

Finally, the Secretary argues mandamus is not appropriate and re-counts the administrative remedy of escalation that is available to Medicare beneficiaries when either an ALJ or the AC does not act timely. The Secretary's argument fails on two fronts. First, the United States Court of Appeals for the District of Columbia Circuit has explicitly rejected the Secretary's argument that escalation is an appropriate remedy. See Amer. Hosp. Ass'n v. Burwell, Civ. 15-5015, D.C. Cir. (Decided Feb. 9, 2016) ("AHA"). In AHA, hospital brought a mandamus action seeking to compel the Secretary to timely adjudicate claims through the Medicare appeals process. The Circuit Court found that applying the relevant factors articulated in Telecommunications Research & Action Center v. F.C.C. (TRAC), 750 F.2d 70, 80 (D.C. Cir. 1984), that the Secretary's purported relief offered through escalation was no relief at all. AHA at 10 – 16. In AHA, hospitals sought to compel the Secretary to adhere to her statutory timelines due to the economic effect on hospital finances. In Ms. Lewis' case the equities are even more compelling – Ms. Lewis and other Medicare beneficiaries are being denied access to health care that is considered the standard of care for their condition. An elderly, ill population, typically living on a fixed income, typically do not have the resources, time or level of sophistication to endure the Secretary's delay in timely adjudicating their claims. Thus, many Medicare beneficiaries will be denied access to needed medical care and will suffer significant health

consequences as a result of the Secretary's failure to meet her non-discretionary statutory deadlines.

2. The Secretary's Failure to Timely Act on Escalation Requests

Independent of the Circuit Court's explicit rejection of the Secretary's position, if the Secretary had produced the administrative record as she is required (but which she has neglected to do), she would have appreciated that Ms. Lewis did attempt to avail herself of the administrative remedy of escalation, but the Secretary again failed to meet the mandated timeline to take an action that vested this court with jurisdiction. Medicare regulations state that within five days of receipt of a request for escalation to district court, the AC may issue a decision, dismissal or remand the case to an ALJ and if it cannot do either of the foregoing, "it will send notice to the appellant acknowledging receipt of the request for escalation and confirming it is not able to issue a decision, dismissal or remand order within the statutory time frame." 42 C.F.R. §405.1132(a)(2). However, only after a party receives the AC required notice, decision, dismissal or remand, may a party seek judicial review. 42 C.F.R. §405.1132(b). On September 14, 2015, after her case had been pending at the AC for over a year, Ms. Lewis filed a request to have her case escalated from the AC to this court. The AC took none of the prescribed actions within the five-day window despite the clear statutory and regulatory mandate. When the Secretary failed to take timely action on her escalation request, and Ms. Lewis questioned its status, the AC representative simply stated it was "working on it." Although the Secretary ultimately issued a decision (albeit untimely) which is pending before this court, the Secretary's

purported escalation remedy has been compromised by the AC and in a manner that deprives Medicare beneficiaries of the ability to have timely judicial review.[5]

3. Mandamus is Appropriate Based on Unresolved Non-Compliance

Finally, the Secretary asserts that because she has completed her administrative process with respect to this claim, mandamus is inappropriate. The Secretary, however, ignores the fact that (1) many Medicare beneficiaries have claims pending in the Medicare appeals process which have not been timely resolved because of the Secretary's failure to meet statutory timelines, and (2) because CGM supplies are refilled on a monthly basis, to the extent any of those claims are denied, Ms. Lewis, and other similarly situated Medicare beneficiaries, continue to be subjected to the effects of the Secretary's failure to meet her statutory obligations. Thus, although the Secretary ultimately completed the Medicare appeal process with respect to this claim (albeit untimely per the regulations), other claims have been or will be subjected to the same or similar delays despite efforts to take advantage of the escalation process.[6]

Ms. Lewis requests that this Court direct the Secretary to render decisions on behalf of Medicare beneficiaries in a timely manner given their need for resolution of Medicare coverage determinations, particularly in view of the recurring claims for supplies for CGM and Medicare beneficiaries dire need for the device.

III. Conclusion

The Secretary points to no evidence, let alone substantial evidence, in support of her denial of Ms. Lewis' claim for CGM. Further, the Secretary cannot cite convincing evidence,

---

[5] To the extent NHIC has a non-coverage policy regarding CGM, which policies are required to be based on a review of the literature, NHIC has conceded, in contravention of the Secretary's directives in the Medicare Program Integrity Manual, §13.7.1, that it did not consider the literature and did not rely on medical opinion when it opined that CGM is precautionary.

[6] The Office of Medicare Hearings and Appeals notes that although Medicare regulations require an ALJ render a decision within 90 days of a request, the average time for resolution exceeds the mandated time. See http://www.hhs.gov/omha/OMHA%20Medicare%20Appellant%20Forum/index.html, October 29, 2014.

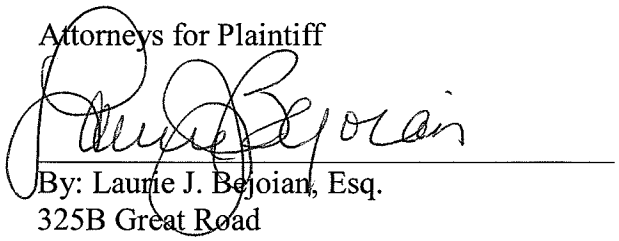
which is required when a coverage policy conflicts with the standard of care, in support of her non-coverage of CGM for Ms. Lewis. The Secretary fails to acknowledge that she has issued multiple final decisions finding CGM is reasonable and necessary (and therefore not precautionary and statutorily excluded) for multiple Medicare beneficiaries who are medically indistinguishable from Ms. Lewis. The Secretary proffers no explanation for her arbitrary, capricious and divergent decisions. Finally, the Secretary ignores her failure to follow prescribed statutory and regulatory timelines for adjudication of Medicare appeals and the consequent frustration of judicial review of the same.

In short, the Secretary's Motion to Dismiss is contrary to the law and reflects fundamental misapprehension of the same. For the foregoing reasons, Ms. Lewis requests that the District Court deny the Secretary's Motion to Dismiss, order the Secretary to produce and certify the administrative record to enable Ms. Lewis to file her Motion for Summary Judgement based on the administrative record, and provide whatever other remedy this Court deems appropriate.

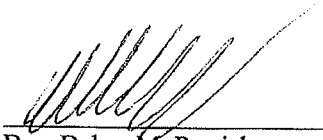
Date: February 17, 2016

Respectfully submitted,

Attorneys for Plaintiff



By: Laurie J. Bejoian, Esq.
325B Great Road
Littleton, MA 01460
TEL 978-486-9145
FAX 978-486-9362
Email: ljblaw.ljbejoian@gmail.com
BBO# 545312



By: Debra M. Parrish
OF COUNSEL
PARRISH LAW OFFICES
788 Washington Road
Pittsburgh, PA 15228
TEL 412-561-6250
FAX 412-561-6253
Email: debbie@dparrishlaw.com